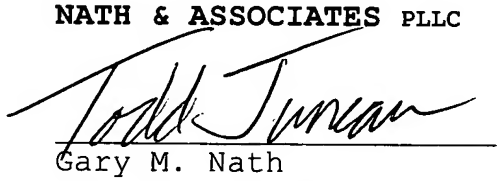
CONCLUSION

In view of the foregoing, applicant respectfully requests the Examiner to allow all claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

NATH & ASSOCIATES PLLC



Gary M. Nath
Reg. No. 26,965
Todd L. Juneau
Reg. No. 40,669
Customer No. 34375

Date: July 1, 2004
NATH & ASSOCIATES PLLC
1030 Fifteenth Street, N.W.
Sixth Floor
Washington, D.C. 20005-1503
Telephone: (202) 775-8383
Facsimile: (202) 775-8396
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submits that the amendments do not add any new matter within the meaning of 35 U.S.C. 132 to the application.

1. Rejection of claim 10 under 35 U.S.C. §112, 1st paragraph

The Official Action states the following, in relevant part:

> Claim 10 is rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement.
>
> Claim 10 is drawn to a method of treating an airway disorder … the recitation 'an airway disorder' includes all airway disorders. It would not be possible to enumerate here all disorders contemplated by this language.

RESPONSE

Applicant respectfully points out to the Examiner that claim 10 has been canceled. Applicant also respectfully points out to the Examiner that new method claims 15-16 and 21-22 have been drafted so that the specific diseases and disorders are listed in a Markush listing. The specific diseases listed in claims 15-16 and 21-22 have basis in the specification at page 45. As a result, one of ordinary skill in the art would be properly enabled to make and/or use the invention as presently claimed.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

2. Rejection of claims 1-10 under 35 U.S.C. §112, 2nd paragraph

The Official Action states the following, in relevant part:

Claims 1-10 are rejected under 35 U.S.C. 112, 2nd paragraph for failing to point out and distinctly claim the subject matter which applicant regards as his invention.

In instant claim 1, Y1 and Y2 are defined as "identical or different and are a 4-11C-heteroaryl or 2-7C-heterocycloalkyl radical containing at least one ring nitrogen..."

Also in claim 1, Z1 and Z2 include as limitations the following moieties: "5-12C heteroarylene...3-8C-heterocycloalkylene..."

Heteroaryl, heterocycloalkyl, heteroarylene and heterocycloalkylene are indefinite.

Claim 1 is also indefinite because though the claim requires 20 to 40 bonds to be present between 'the terminal nitrogen' atoms in the compound of formula I, a compound according to formula I need not have any terminal nitrogen atoms, or may only possess one terminal nitrogen atom.

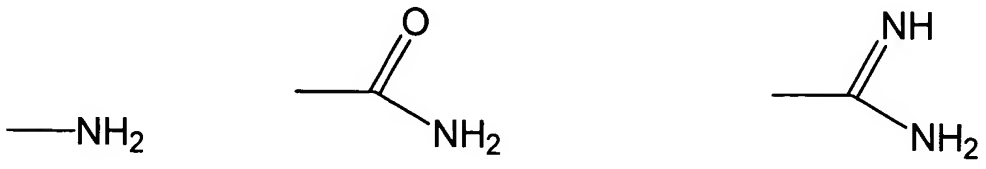
The requirement of there having to be 20 to 40 bonds present between the terminal nitrogen atoms is further indefinite because it is unclear which nitrogen atoms are to be considered terminal, since the variables X1 and X2 include eight different functional groups which terminate in more than one nitrogen atom. It is unclear which of the nitrogen atoms in these particular functional groups is to be considered the "terminal nitrogen atom(s)". A logical problem also arises from the fact that within the multi-nitrogen atom-terminated groups X1 and X2, there are two terminal nitrogen atoms. It would not be possible for 20 to 40 bonds to be present between these nitrogen atoms (which are terminal) that are separated by only a few other atoms, yet this particular configuration is in fact claimed.

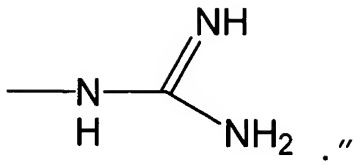
RESPONSE

Applicant respectfully points out to the Examiner that claims 1-10 have been cancelled. In applicant's new claims 11-22, there is no claim with the aforementioned terms (such as "5-12C heteroarylene") that formed the basis of this rejection. Further, the subject matter of claim 1 (the only claim that contained such allegedly indefinite language) has been cancelled without prejudice or disclaimer.

Further, the definitions of Y1 and Y2 (possible 'terminal' points of the substituents K1 and K2, respectively) have been amended to read "imidazol-1-yl". Thus, Y1 and Y2 clearly must possess a nitrogen atom.

Regarding the Examiners comment that "It is unclear which of the nitrogen atoms in these particular functional groups is to be considered the "terminal nitrogen atom(s)", applicant respectfully point out to the Examiner that the present claims are definite in this respect. For example, claim 11 defines X1 and X2 as being "identical or different and are selected from the groups below





."

Only two of these variables have more than one nitrogen atom and one of ordinary skill in the art would clearly know which nitrogen atom is the "terminal" nitrogen atom. It would also be readily apparent to a person of ordinary skill that choosing one nitrogen atom over the other as the "terminal" nitrogen atom is really of no consequence. This is because in both "multi-nitrogen" containing substituents, the two nitrogen atoms which could be chosen as the "terminal" nitrogen would yield the same bond count no matter which nitrogen was chosen to be the "terminal" nitrogen. This is especially true in view of the claim language which reads "and where on the direct route along the bonds between the terminal nitrogen atom as defined in K1 on the one hand and the terminal nitrogen atom as defined in K2 on the other hand, 20 to 40 bonds have to be present, wherein each double bond is counted as one bond and each triple bond is counted as one bond".

This language also addresses the Examiner's other comment regarding the "logical problem" that arises from the fact that

within the multi-nitrogen atom-terminated groups X1 and X2. It is now clear from the way the claim reads that only one terminal nitrogen atom is defined by K1 and only one terminal nitrogen atom is defined by K2.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

3. Rejection of claims 1-2 under 35 U.S.C. §102(b)

The Official Action states that claims 1-2 have been rejected under 35 U.S.C. §102(b) as being anticipated by Rodbotten et al. and Crisp et al.

Applicant respectfully points out to the Examiner that claims 1-2 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 1-2 have been cancelled solely to remove this rejection and expedite the allowance of the claims pending in this application. Claims 1-2 were not cancelled because applicant agrees with the Examiner's position regarding the interpretation of the Rodbotten et al. and Crisp et al. references.

Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

hydrate, salt, hydrate of a salt, or solvate of a salt thereof,

wherein the compounds in which one or more of the variables B1, B2, B3, B4, B5, B6, B7, B8, B9, B10, B11 or B12 may assume the meaning of a bond resulting in the direct linkage of two heteroatoms or carbonyl groups are excluded.

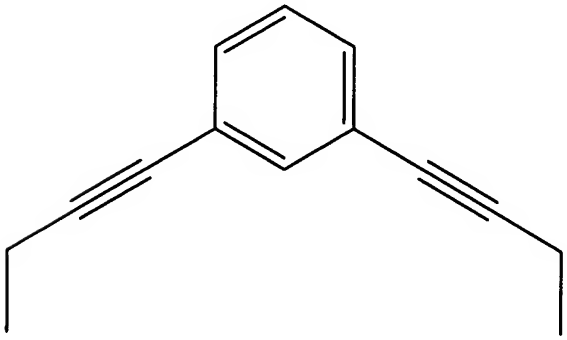
12. (New) A compound of formula I according to claim 11, in which

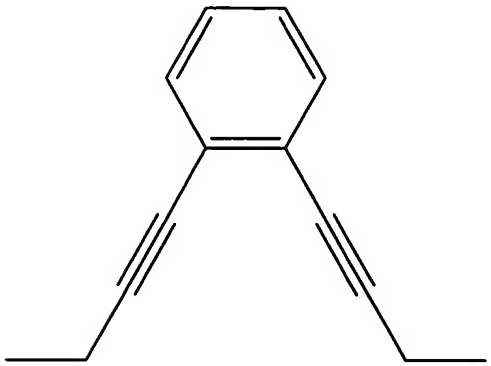
A1 and A2 are -O-C(O)-,

A3 and A4 are 1,4-piperazinylene,

A5 and A6 are identical or different and are -C(O)- or -C(O)-NH-,

M is a central building block selected from the groups below





K1 is $-B7-(C(O))_m-B9-Z1-B11-X1$,

K2 is $-B8-(C(O))_p-B10-Z2-B12-X2$,

B1, B2, B3, B4, B5 and B6 are a bond,

B7 and B8 are identical or different and are a bond or methylene,

B9 and B10 are a bond,

B11 and B12 are methylene,

m is 0,

p is 0,

X1 and X2 are amino,

Z1 and Z2 are identical or different and are 1,4-phenylene or 1,4-cyclohexylene,

or a solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof.

13. (New) A compound of formula I according to claim 11 with the chemical name

1,2-bis[4-trans-4-aminomethylcyclohexylcarbonyl)-1-piperazinylcarbonyl-1-oxyprop-2ynyl]benzene;

1,4-bis[4-trans-4-aminomethylcyclohexylcarbonyl)-1-piperazinylcarbonyl-1-oxyprop-2ynyl]benzene;

1,2-bis[4-(4-aminomethylbenzylaminocarbonyl)-1-piperazinylcarbonyl-1-oxyprop-2ynyl]benzene;

1,3-bis[4-(4-aminomethylbenzylaminocarbonyl)-1-piperazinylcarbonyl-1-oxyprop-2ynyl]benzene;
or a solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof.

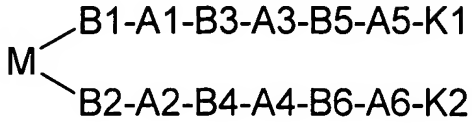
14. (New) A pharmaceutical composition comprising a compound of claim 11 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof, or an N-oxide of a compound of claim 11 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt or solvate of a salt thereof; and a suitable pharmaceutical excipient.

15. (New) A method of treating a disease or disorder in a patient comprising administering to a patient in need thereof a therapeutically effective amount of a compound of claim 11 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof,
or an N-oxide of a compound of claim 11 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt or solvate of a salt thereof,
wherein the disease or disorder is selected from the group consisting of bronchitis, allergic bronchitis, asthma, bronchial asthma, COPD, allergic conjunctivitis, allergic rhinitis, arthritis, rheumatoid arthritis, periodontitis, anaphylaxis, interstitial cystitis, dermatitis, psoriasis, sclerodermatitis, Crohn's disease and inflammatory bowel disease.

16. (New) The method of claim 15, wherein the disease or disorder is selected from the group consisting of

bronchitis, allergic bronchitis, asthma, bronchial asthma, and COPD.

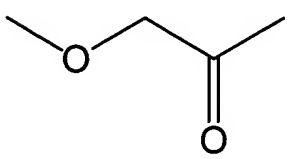
17. (New) A compound of formula I

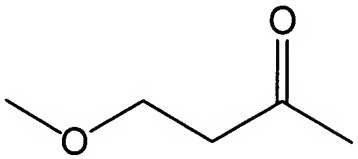


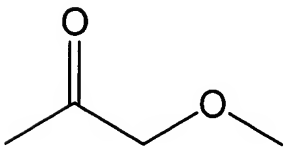
(I)

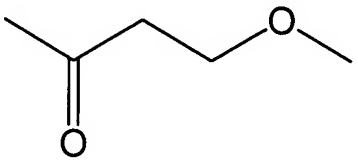
in which

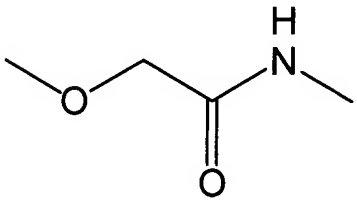
-B1-A1-B3-A3-B5-A5- and -B2-A2-B4-A4-B6-A6- are identical or different and are selected from the groups below

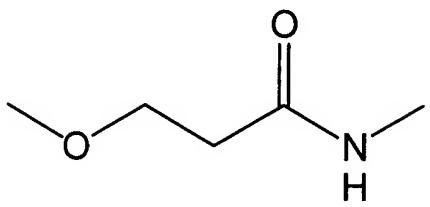


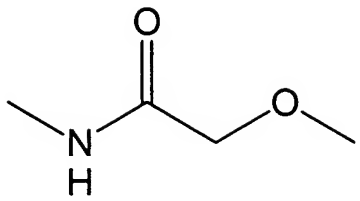
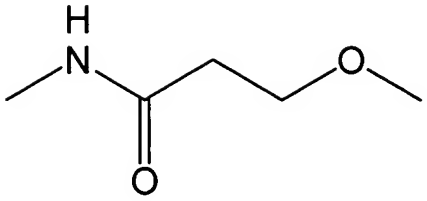
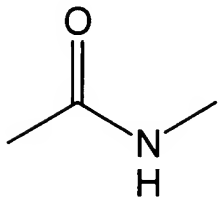
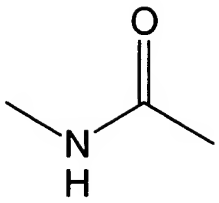
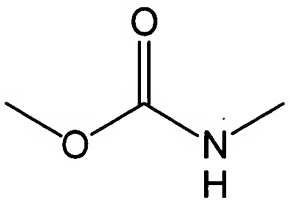
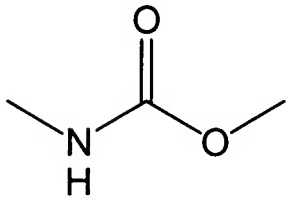
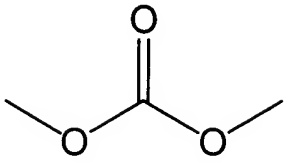
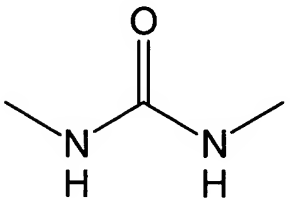




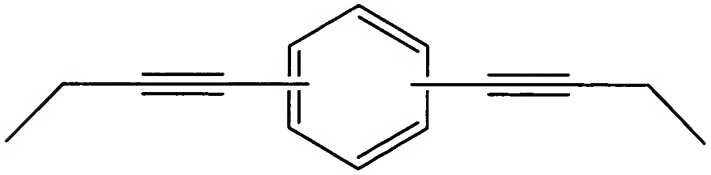






M is the central building block



K1 is $-B7-(C(O))_m-B9-Y1$ or $-B7-(C(O))_m-B9-Z1-B11-X1$,

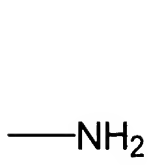
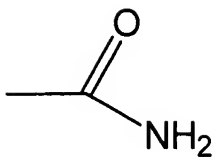
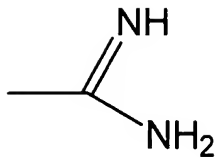
K2 is $-B8-(C(O))_p-B10-Y2$ or $-B8-(C(O))_p-B10-Z2-B12-X2$,

B7, B8, B9, B10, B11 and B12 are identical or different and are a bond or 1-2C-alkylene,

m is 0,

p is 0,

X1 and X2 are identical or different and are selected from the groups below

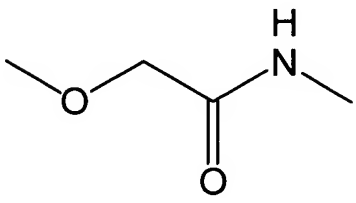
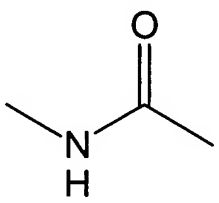
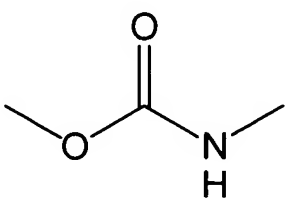
Y1 and Y2 are imidizol-1-yl,

Z1 and Z2 are identical or different and are 5,2-pyridinylene, 6-methyl-5,2-pyridinylene, 4,1-piperidinylene, 3,6-indazolylene, 3,6-indolylene, 1,3-phenylene, 1,4-phenylene, 1,3-cyclohexylene or 1,4-cyclohexylene,

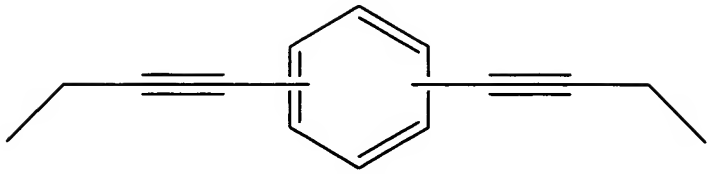
and where on the direct route along the bonds between the terminal nitrogen atom as defined in K1 on the one hand and the terminal nitrogen atom as defined in K2 on the other hand, 20 to 40 bonds have to be present, wherein each double bond is counted as one bond and each triple bond is counted as one bond, or a solvate, hydrate, salt, hydrate of a salt or solvate of a salt thereof, or an N-oxide of the nitrogen-containing heteroaryls, heterocycloalkyls, heteroarylenes and heterocycloalkylenes, or a solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof.

18. (New) A compound of formula I according to claim 17 in which

-B1-A1-B3-A3-B5-A5- and -B2-A2-B4-A4-B6-A6- are identical or different and are selected from

M is the central building block



K1 is $-B7-(C(O))_m-B9-Z1-B11-X1$,

K2 is $-B8-(C(O))_p-B10-Z2-B12-X2$,

B7 and B8 are identical or different and are a bond or methylene,

B9 and B10 are a bond,

B11 and B12 are methylene,

m is 0,

p is 0,

X1 and X2 are amino,

Z1 and Z2 are identical or different and are 1,4-phenylene or 1,3-phenylene,

or a solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof.

19. (New) A compound of formula I according to claim 17 with the chemical name

1,3-Bis-(4-aminomethylbenzylaminocarbonyl-1-oxyprop-2-ynyl)-benzene;

1,2-Bis-(4-aminomethylbenzylaminocarbonyl-1-oxyprop-2-ynyl)-benzene;

1,4-Bis-(4-aminomethylbenzylaminocarbonylmethyl-1-oxyprop-2-ynyl)-benzene;

1,3-Bis-(4-aminomethylbenzylaminocarbonylmethyl-1-oxyprop-2-ynyl)-benzene;
1,4-Bis-(4-aminomethylbenzylcarbonyl-1-aminoprop-2-ynyl)-benzene;
1,2-Bis-(4-aminomethylbenzylcarbonyl-1-aminoprop-2-ynyl)-benzene;
1,4-Bis-(4-aminomethylphenylethylcarbonyl-1-aminoprop-2-ynyl)-benzene;
or a solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof.

20. (New) A pharmaceutical composition comprising a compound of claim 17 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof, or an N-oxide of a compound of claim 17 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt or solvate of a salt thereof; and a suitable pharmaceutical excipient.

21. (New) A method of treating a disease or disorder in a patient comprising administering to a patient in need thereof a therapeutically effective amount of a compound of claim 17 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt, or solvate of a salt thereof,
or an N-oxide of a compound of claim 17 or a pharmaceutically acceptable solvate, hydrate, salt, hydrate of a salt or solvate of a salt thereof,
wherein the disease or disorder is selected from the group consisting of bronchitis, allergic bronchitis, asthma, bronchial asthma, COPD, allergic conjunctivitis, allergic rhinitis, arthritis, rheumatoid arthritis, periodontitis,

anaphylaxis, interstitial cystitis, dermatitis, psoriasis, sclerodermatitis, Crohn's disease and inflammatory bowel disease.

22. (New) The method of claim 21, wherein the disease or disorder is selected from the group consisting of bronchitis, allergic bronchitis, asthma, bronchial asthma, and COPD.